EARLY CLINICAL EXPERIENCE WITH A NEW SUTURELESS ANASTOMOTIC DEVICE FOR PROXIMAL ANASTOMOSIS OF THE SAPHENOUS VEIN TO THE AORTA

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Background: Avoiding aortic side clamping in useful to avoid local particulate embolization. A device that allows a saphenous vein graft to be anastomosed to the aorta without aortic manipulation is clinically evaluated.

Methods and results: From July 1999 to March 2000, 17 patients who underwent myocardial revascularization had an aorta–saphenous vein graft anastomosis performed by means of an aortic anastomotic device. Eight were operated on with cardiopulmonary bypass and 9 without. The proximal anastomoses created by the aortic anastomotic device were performed before the institution of cardiopulmonary bypass or before the related distal anastomosis was performed. In 11 patients transcranial Doppler ultrasound was used. In 1 (6%) patient the saphenous vein graft was not deployed, and in 2 (12%) a single suture was added for minor bleeding. None of the 11 patients evaluated with transcranial Doppler ultrasound had evidence of particulate embolization during the procedure. No patient died or was reoperated on for bleeding. Six (35%) patients had a postoperative angiogram 48 ± 26 days after the operation that showed widely patent proximal anastomoses.

Conclusions: Use of an aortic anastomotic device allows a sutureless anastomosis to be created between the aorta and saphenous vein graft. The device could be used in totally endoscopic myocardial revascularization. A second-generation device is ready to solve the problems encountered and to increase the ease in handling the device. (J Thorac Cardiovasc Surg 2001;121:854-8)

Side clamping of the ascending aorta is recognized as a possible cause for the increased incidence of perioperative cerebrovascular accidents during myocardial revascularization.[1,2] When cardiopulmonary bypass (CPB) is used, the proximal anastomosis of the saphenous vein can be performed with a single episode of crossclamping, avoiding further trauma to the ascending aorta. However, when the procedure is done without CPB, aortic side clamping cannot be avoided if a saphenous vein graft (SVG) is used.

A new sutureless aortic anastomotic device (AAD; Bypass, Ltd, Herzelia, Israel) that allows an anastomosis to be created to the proximal aorta with an SVG, without aortic manipulation, was designed. We herein report our clinical experience.

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Material and methods

Description of the AAD. The AAD is a self-expanding nitinol extraluminal device that consists of a central cylindrical body made of interconnected elliptical arches and 2 sets of 5 pins (0.3 mm thick) radiating from each end (Fig 1). The stent has an unreleased diameter of about 3.5 mm and a released diameter of 5.3 mm. The initial version of the device enables the surgeon to perform the proximal anastomosis only before the distal one.

With the use of a tubular delivery system, the AAD being housed in a cartridge at its distal end, an SVG is prepared for anastomosis by being inserted through the delivery system and the central part of the AAD, with its proximal 2 to 3 mm everted over the distal end of the delivery system. The 5 inner pins of the AAD are then exposed from the cartridge of the delivery system, a maneuver that makes them protrude and penetrate the everted segment of the vein (Fig 2). The device has to be assembled before use. The vein is mounted on the delivery system before punching, a procedure that takes 4 to 5 minutes.

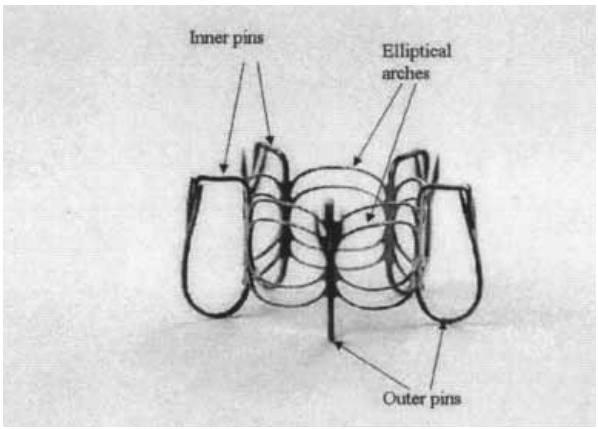

Fig 1. The AAD.

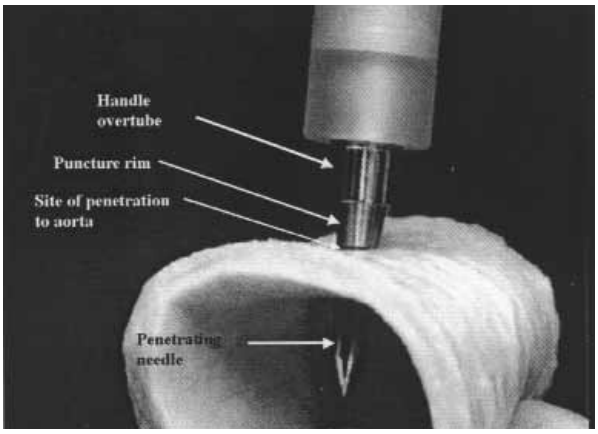

Fig 3. The punching instrument, inserted in the handle, penetrates the aorta. Both the vein and aorta are from a cadaver.

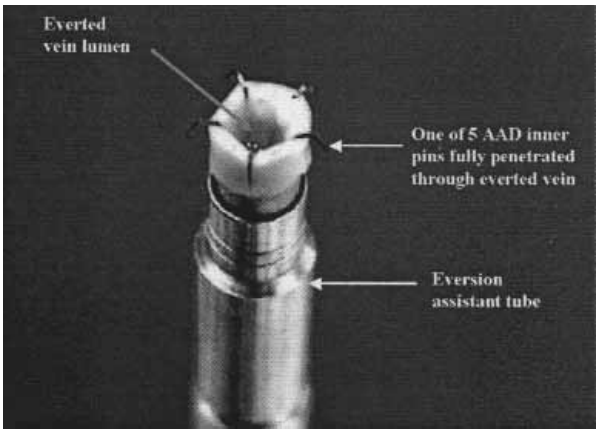

Fig 2. The distal end of the vein is everted and the inner pins are allowed to fully penetrate the vein wall. Both the vein and aorta are from a cadaver.

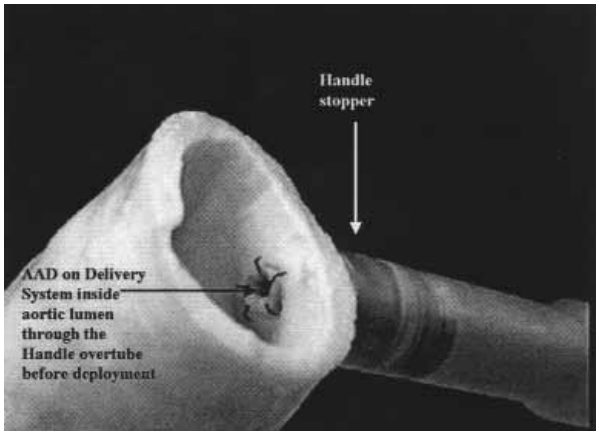

Fig 4. The AAD inside the aortic lumen (before deployment) after being inserted through the handle with its covering tube protruding in the aortic lumen.

A special penetrating and punching device inserted through a guiding handle creates a 3.2-mm punched out hole in the unclamped aortic wall (Fig 3). The punching instrument is then withdrawn from the handle, and backflow from the aorta is prevented by a sealing ring placed in the handle. Then, the delivery system loaded with the vein is advanced through the tubular guiding handle into the lumen of the aorta. Once inside the lumen, the AAD is fully released from its cartridge within the delivery system, a maneuver that places the AAD within the aortic wall, with all pins fully extended (Fig 4). The inner pins are inside the aorta, partially penetrating the inner aortic wall (Fig 5), while the outer pins stabilize the device by anchoring into the aortic adventitia (Fig 6). The punching and deployment can be performed by one person in less than 1 minute.

Because the punched out hole has a diameter of 3.2 mm while the maximal diameter of the self-expanding AAD is 5.3 mm, the central cylindrical component expands, thus exerting radial pressure on the everted segment of the vein, pressing it toward the aortic wall, and sealing it circumferentially.

After the release of the AAD, the vein, now filled with blood, is fully extracted from the delivery system and the guiding handle and is ready to be anastomosed at its distal end. In this initial version, the angle that the SVG forms with the ascending aorta is about 90°.

Clinical experience. Patients were accepted for this operation according to clinical protocol previously approved by the ethical committee, and the study was conducted according to the European Standard EN 540 "Clinical Investigation of Medical Devices for Human Subjects" and the Declaration of Helsinki. Before being involved in the study, patients were informed of the purpose, rights, duties, strategies, and possible risks and then confirmed their consent in writing. To be included in the study, patients had to fulfill all the inclusion criteria and none of the exclusion criteria.

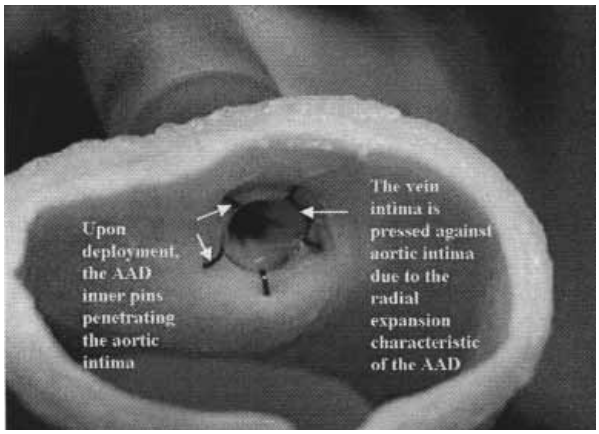

Fig 5. The AAD after deployment from the delivery system, as seen from the aortic lumen. The pins allow contact between the intimas of the vein and of the aorta.

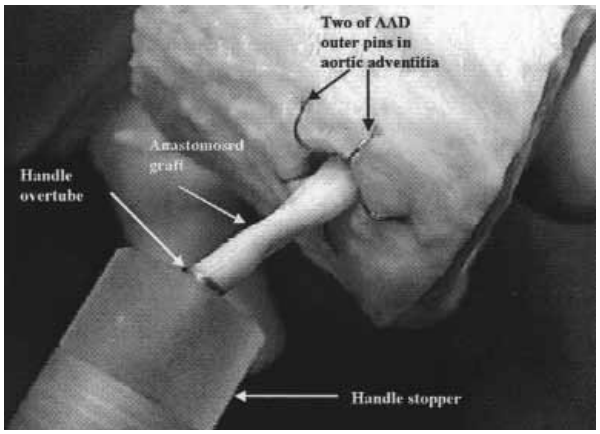

Fig 6. The outer pins stabilize the device by anchoring into the aortic adventitia.

Table I. *Clinical and operative data*

Age (y)	62.1 ± 8.8
Female sex	4 (23.5%)
Unstable angina	4 (23.5%)
Ejection fraction	63.2 ± 6.4
Repeat operation	1 (5.8%)
Anastomoses/patient	2.6 ± 0.7
On/off pump	8/9

Table II. *Technical details*

Device unreleased	1 (5.8%)
Leakage	2 (11.7%)
Perfect device release	14 (82.5%)

Table III. *SVG distal anastomoses*

Total distal anastomoses	18 (2 sequential)
Posterior descending artery	9 (50.1%)
Obtuse marginal	6 (33.3%)
Right coronary artery	2 (11.1%)
Diagonal branch	1 (5.5%)

Inclusion criteria

- Patients have to be scheduled for primary elective isolated coronary artery bypass grafting
- Patients have to agree to attend the follow-up evaluations and sign an informed consent form

Exclusion criteria

- Emergency operation
- Not a standard isolated coronary bypass operation
- Life expectancy of less than 2 years
- Previous coronary bypass operation
- Participation in another drug or device study
- Severe aortic atherosclerosis in the target anastomotic site
- Some contraindication to use of antiplatelet drugs
- Chronic renal failure

From July 1999 to March 2000, 17 patients who underwent myocardial revascularization were scheduled to have the AAD used to perform the proximal anastomosis of the SVG. Clinical data are shown in Table I.

Eight patients were operated on with and 9 without CPB. In all cases the AAD proximal anastomoses were performed before the institution of CPB and before the distal anastomoses were performed. Eleven patients had transcranial Doppler ultrasonography to detect microemboli during aortic punching with the AAD.

Statistical analysis. Results are expressed as mean ± SD unless otherwise indicated.

Results

Use of the AAD for proximal anastomosis of the SVG was attempted in 17 patients and was successful in 16. In 1 (5.6%) patient the vein was deployed incorrectly because the aortic wall was very thick, but the hole was easily controlled with sutures. Perioperative use of an epicardial echo probe could be helpful to check the thickness and the quality of the aortic wall. Because such a probe is not available in all operating rooms, we suggested that the manufacturer increase the length of inner pins by about 1 mm so that the device can be used safely when the aortic wall is thicker than normal. In 2 cases, one stitch was necessary because of minor leakage. Technical details are shown in Tables II and III. None of the 11 patients in whom transcranial

Doppler ultrasonography was used had particulate embolization during aortic punching.

After a mean follow-up period of 4 ± 2 months, no patient had died or required reoperation for bleeding. None of the patients had any symptoms of angina during the follow-up period.

Six (35.3%) patients had a follow-up angiogram (48 ± 26 days postoperatively). The conduits were all widely patent (Fig 7).

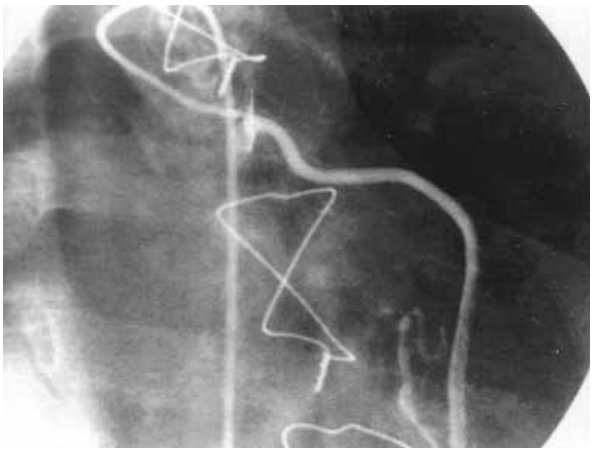

Fig 7. Postoperative angiogram. The proximal anastomosis is patent; the vein arises at a 90° angle from the aorta, as indicated by the contrast material in the vein.

Discussion

The search for a device that can facilitate vascular anastomoses is not new. Over the years many authors have designed and used many techniques, both experimentally and clinically, to bond blood vessels of different sizes. Stapling, clipping, coupling, pasting, and laser welding have been used, with not completely acceptable results.[3] Recently, a one-shot anastomotic device for end-to-side coronary anastomosis was designed and commercialized,[4,5] but its use is confined to arteriovenous fistulas for vascular access.

Our approach started from the easiest part of the problem, with the purpose of designing a stapling device that allowed an end-to-side anastomosis between the aorta and an SVG that has a relatively big internal size. There are several advantages. Aortic manipulation and, in particular, aortic side clamping[4] are considered the main causes of intraoperative cerebral embolization during myocardial revascularization with CPB and are correlated to increased length of stay and higher incidence of adverse neurologic postoperative outcome.[5] In our clinical experience, we found that the AAD is useful for creating a proximal SVG-aorta anastomosis, eliminating the need for aortic side clamping. This can be valuable in myocardial revascularization without CPB because of the risk of particulate embolization with side clamping when the SVG is used. The maneuvers connected with the use of the device (aortic punching) did not cause microembolization from the aorta in any of the patients in whom emboli were sought.

The second advantage is the ability to use the aorta as a blood source in endoscopic surgery, allowing the saphenous vein to be used as an aorta-coronary graft, when necessary.

This device is a first-generation AAD. A second generation will be available shortly, which will address the two issues that were encountered in the current generation: immediate leakage encountered in 2 cases and incorrect deployment in 1 case. We believe that a thicker-than-normal aortic wall was responsible for the incorrect deployment of the AAD. The leakages can be related to the single size of the delivery system. When the saphenous vein is small, the system cannot be used, but it can be used when the saphenous vein is larger than the AAD. This mismatch between the AAD and the vein can cause bleeding due to shrinkage of the vein, a problem that will be solved with the next generation of the device. A small vein cannot fit the delivery system; for this reason we encountered no instances of rupture of the vein due to inadequate size.

Other modifications will be part of the second-generation AAD:

- The angle between the implanted SVG and the aortic surface is currently about 90°. Although this works well, the graft needs to be directed in an acute angle. Currently, it is mandatory to choose the right location of the proximal anastomosis very carefully so that the SVG will be oriented as much as possible toward the target coronary artery. This is a limitation of the current AAD, especially with an atheromatous or short aorta.
- The possibility to perform the distal anastomoses first.
- At least 2 different sizes of AAD to widen SVG usage, limited now by the width of the vein. At present, only one size is available; therefore, a small-diameter vein (<3 mm) is a contraindication to use of the device.
- Lengthening of the covering tube of the handle to allow a thicker aortic wall to be deployed with the AAD. As mentioned earlier, in the only case in which the device was unreleased, the aortic wall was very thick and diseased.

In conclusion, the AAD allows a sutureless SVG anastomosis. The results presented here show clearly that the AAD-mediated aorta-SVG anastomosis works

successfully, and all the clinical outcomes were satisfying. None of the patients had symptoms of angina, and those grafts that were reviewed angiographically were fully patent. A second generation of the AAD will be available shortly and will address the above-mentioned improvements.

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Discussion

Dr Robert W. Emery *(Minneapolis, Minn).* Do you think this device is going to change the way we approach coronary surgery? This will change the proximal anastomoses. Are we going to need to directly visualize the ascending aorta in the future?

Dr Calafiore. The manipulation, as seen in the aorta, is one of the points that must be discussed to simplify myocardial revascularization, especially in the beating heart. In some cases the quality of the aorta is poor. In other cases some of the arterial conduits needed for complete revascularization are unavailable because of age or comorbidities. The possibility of using the ascending aorta as a blood source for an SVG without side clamping is appealing. As the AAD is further developed, I hope it will be helpful. I do not know whether it will have a great impact, but in some patients it can surely be helpful.

Dr Emery. It seems to me the impact will be quite large.

Dr Valvanur A. Subramanian *(New York, NY).* Is this the same device that Naresh Trehan used in Delhi? One of the anastomoses fell apart during the middle of the night and the patient had to be resuscitated.

Dr Calafiore. I know that Naresh Trehan treated 2 patients. He does not know the reason for the failure in the 1 patient. He told me that this device was perfectly reasonable. Our group worked for a few months and had only 17 patients because of the limitations of the device and the need to obtain the consent of the patients. However, we never observed any complications such as you mentioned. Those devices that we observed in the operating room remained normal. In Dr Trehan's case, I think the AAD may not have been perfect.